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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/732,802	12/11/2003	Gonzalo Serafica	505827-0007	5886

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EXAMINER

ALSTRUM ACEVEDO, JAMES HENRY

ART UNIT	PAPER NUMBER
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1616

MAIL DATE	DELIVERY MODE
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09/18/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/732,802	Applicant(s) SERAFICA ET AL.	
	Examiner JAMES H. ALSTRUM ACEVEDO	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6/22/09.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 26-31, 33-34, and 37-39 is/are rejected.
- 7) ☒ Claim(s) 36 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claims 1-11, 19, 26-31, and 33-34 are pending. Applicants previously cancelled claims 12-18, 20-25, 32, and 35. Receipt and consideration of Applicants' amended claim set, new IDS, and remarks/arguments submitted on June 22, 2009 are acknowledged. All rejections not explicitly maintained in the instant office action have been withdrawn per Applicants' claim amendments.

Terminal Disclaimer(s)

The terminal disclaimer filed on June 22, 2009 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of copending Application No. 10/864,804 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 19 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 4 of U.S. Patent No. 7,510,725 (USPN '725) in view of Orr III (U.S. Patent No. 6,369,289) ("Orr"). Independent claims 19 of the instant application claims a method of producing a wound dressing kit comprising (i) statically producing microbial cellulose pellicle using *Acetobacter xylinum*, (ii) isolating the microbial cellulose pellicle with a cellulose to water ratio in the range of 1:100 to 1:500, (iii) depyrogenating the isolated microbial cellulose pellicle, (iv) drying the isolated microbial cellulose pellicle to a cellulose content of 1.5-4.5% w/w, (v) placing the dressing into a moisture proof package, and (vi) providing instructions on the treatment of chronic wounds. Independent claim 1 of USPN '725 claims a method of producing a dural substitute comprising (a) producing a cellulosic material from a culture of *Acetobacter xylinum*, (b) removing contaminants from the cellulose material by contacting the cellulose material with a caustic solution and subsequently contacting with water to rinse said cellulosic material (i.e. depyrogenating), (c) removing at least a portion of the water from the cellulose material by (i) freezing moisture in the cellulose material, (ii) melting at least a portion of the frozen moisture, and (iii) removing at least a portion of the melted moisture, whereby the cellulose material is a cellulosic sheet, mesh, or film (pellicle). Dependent claim 4 of USPN '725 specifies that the step of removing the contaminants renders the dural substitute non-pyrogenic.

The primary differences between the claimed method of claim 19 of the instant application and claim 1 of USPN '725 are that (1) step (a) of USPN '725 is not specified as being

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static, (2) step (b) of USPN '725 claim 1 is an additional depyrogenating step, and (3) USPN '725 lacks the step of placing the dressing in a moisture proof package and providing instructions. Regarding deficiency (1) the specification of USPN '725 specifies that the production of the cellulose material from *Acetobacter xylinum* occurs in a fermentation bioreactor under static conditions (col. 4, lines 25-20). Thus, statically practicing the first step in the claimed process of claim 19 of the instant application is an obvious modification of step (a) of claim 1 of USPN '725. Regarding the second difference, claim 19 of the instant application uses open comprising language, and so does not exclude additional steps.

Regarding the third difference, this deficiency is also *prima facie* obvious, because common sense would lead one to place a cellulose material containing water in a moisture-proof package to prevent the water from evaporating. The step of providing instructions is not given any patentable weight. It is the Examiner's and the Office's position that the inclusion of instructions are not a patentably distinguishing feature. This position is also supported by case law (see *In re Ngai*, 70 USPQ2d 1862 (CA FC 2004)). Therefore, a person of ordinary skill in the art at the time of the instant invention would have found claim 19 *prima facie* obvious over claims 1 and 4 of USPN 7,510,725.

Allowable Subject Matter

Claims 1-11, 26-31, 33-34, and 37-39 are allowed, based on the unexpected liquid donation and absorption properties of cellulosic wound dressings comprising 1.5-4.5% w/w microbial cellulose, as explained further below.

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Claim 36 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The aforementioned claims are considered to be allowable, because the closest prior art reference (Ring et al., U.S. Patent No. 4,588,400), although generally suggesting the microbial cellulose materials may exhibit moisture donation and liquid absorption properties does not provide any guidance or suggestion as to how to tune these properties by varying the amount of microbial cellulose in a medical product, such as a wound dressing, or suggest making wound dressings having the recited amount of microbial cellulose would exhibit the recited donation properties. Furthermore, Ring teaches a broad range for the amount of microbial cellulose and does not suggest the specific range recited in Applicants' claims would exhibit a particular combination of liquid absorption and moisture donation properties. Finally, the data in Applicants' figure 1 demonstrates the unexpected correlation between the amount of microbial cellulose in a wound dressing and the exhibited moisture donation and liquid absorption properties, as recited in claim 1 of the instant application.

Conclusion

Claim 19 is rejected. Claim 36 is objected. Claims 1-11, 26-31, 33-34, and 37-39 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, ~10:00-6:00 and Saturdays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/James H Alstrum-Acevedo/
Patent Examiner, Art Unit 1616
Technology Center 1600